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A randomised placebo-controlled study of Tamsulosin, Voltarol and the combination in types IIIa and IIIb prostatitis using the newly developed and validated National Institutes of Health (NIH) symptom score

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/01/2020	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0544074138

Study information

Scientific Title
-

Study objectives
Alpha blockers and Voltarol in treating chronic prostatitis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Prostatitis

Interventions
The study is a randomised controlled trial using four arms in the treatment of chronic pelvic pain syndrome in men:

1. Placebo only
2. Tamsulosin
3. Voltarol
4. Tamsulosin and Voltarol

The study will require the usual investigations for chronic prostatitis, and then a 6-week randomisation period in one of the four arms of treatment, taking a total of four tablets a day. The main outcome measure will be a reduction in the National Institute of Health Chronic Prostatitis Symptom Index (NIHCPSI), which is a newly produced and validated symptom score for assessing men with this condition.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tamsulosin, Voltarol

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
03/11/2003

Eligibility

Key inclusion criteria
60 patients aged between 30 and 50

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
04/05/2000

Date of final enrolment
03/11/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Box No 43
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration